IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: H. Michael SHEPARD

Title: METHODS FOR TREATING

THERAPY-RESISTANT

TUMORS

Appl. No.: 10/048,033

International 7/21/2000

Filing Date: 371(c) Date:

Examiner: Crane, Lawrence E.

Art Unit: 1623

Confirmation 2767

Number:

Laura Davis
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August 30, 2007
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56

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Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR

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§1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(c), before the mailing date of either a final action under 37 CFR §1.113, a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application.

RELEVANCE OF EACH DOCUMENT

U.S. Patent Reference #1 (6,589, 941) is the equivalent of foreign-language reference #15 (WO 96/23506). An English translation of the foreign-language document is not readily available. However, the absence of such translation does not relieve the PTO from its duty to consider the submitted foreign language document (37 CFR §1.98 and MPEP §609).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP \$609.

FEE

Fees in the amount of \$180.00 in accordance with 37 CFR §1.17(p) to cover the fee associated with an information disclosure statement under 37 CFR §1.97(c) are being paid by credit card via EFS-Web.

Atty. Dkt. No. 060925-0601

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Attorney for Applicant

Registration No. 34,202

FOLEY & LARDNER LLP

Customer Number: 38706 Telephone: (650) 251-1129 Facsimile: (650) 856-3710

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	Substitute for form	1449/F	OTO		Complete if Known
	INFORMATION DIS	SCLO	SURE	Application Number	10/048033
	STATEMENT BY A	APPLIC	CANT	Filing Date	7/21/2000
	Date Submitted: Aud	et 20	2007	First Named Inventor	H. Michael Shepard
	Date Submitted, Aug	just st), 2007	Art Unit	1623
	(use as many sheets	as nec	cessary)	Examiner Name	Crane, Lawrence E.
Sheet	1	of	5	Attorney Docket Number	060925-0601

Cite	Document Number	Publication Date	Name of Patentee or Applicant of	Pages, Columns, Lines, Where Relevant	
No.1	Number-Kind Code ² (if known)	MM-DD-YYYY	Cited Document	Passages or Relevant Figures Appear	
P1	6,589,941	Fahrig et al.	07-08-2003		
P2	6,599,499	Rosen et al.	07-29-2003		
P3	6,677,314	Klecker et al.	01-13-2004		
P4	6,677,315	Klecker et al.	01-13-2004		
P5	6,682,715	Klecker et al.			
P6	6,683,045	Klecker et al.	01-27-2004		
P7	6,683,061	Shepard et al.	01-27-2004		
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	UNPUBLISHED U.S. PATENT APPLICATION DOCUMENTS								
Examiner Initials*	Cite No.1	U.S. Patent Application Document Serial Number-Kind Code ² (if known)	Filing Date of Cited Document MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear				

FOREIGN PATENT DOCUMENTS										
Cite No.1	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Te					
F15	WO 96/23506	08-08-1996	Fraunhofer Society for the Promotion of Applied Research E.V. (English Abstract)							
	No.1	No. ¹ Country Code ³ Number ⁴ Kind Code ⁵ (If known)	Cite No. 1 Foreign Patent Document Country Code* Number* Kind Code* (# known) Publication Date MM-DD-YYYY	Cite No.1 Foreign Patent Document Country Code* Number* Kind Country Code* (Mnown) Publication Date MM-DD-YYYY Name of Patentee or Applicant of Cited Documents Code* (Mnown) F15 WO 96/23506 08-08-1996 Fraunhofer Society for the Promotion of Applied Research E.V. (English)	Cite Foreign Patent Document Country Code* (Number*Kind Code* (Irknown)					

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	INFORMATION DI	SCLO	SURE	Application Number	10/048033			
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	(use as many sheets	as ne	cessary)	Examiner Name	Crane, Lawrence E.			
Sheet	2	of	5	Attorney Docket Number	060925-0601			

		NON PATENT LITERATURE DOCUMENTS	
Examin er Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	D16	BALZARINI et al. "Highly Selective Cytostatic Activity of (E)-5-(2-Bromovinyl)-2'-deoxyuridine Derivatives for Murine Mammary Carcinoma (FM3A) Cells Transformed with the Herpes Simplex Virus Type 1 Thymidine Kinase Gene" Molecular Pharmacology (1995) 28:581-585	
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	D27	CURT "Cancer drug development: new targets for cancer treatment" Oncologist 1(3):II-III (1996)	_

Examiner	Date Considered	
Signature	Considered	

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7	Substitute for form	1449/	то	Complete if Known				
	INFORMATION DIS	SCLO	SURE	Application Number	10/048033			
	STATEMENT BY A	PPLI	CANT	Filing Date	7/21/2000			
	Date Submitted: Aud	uset 3	2007	First Named Inventor	H. Michael Shepard			
	Date Submitted. Aug	just 5	5, 2007	Art Unit	1623			
(use as many sheets as necessary)				Examiner Name	Crane, Lawrence E.			
Sheet	3	of	5	Attorney Docket Number	060925-0601			

		NON PATENT LITERATURE DOCUMENTS	
Examin er Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
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	D39	LIBRA, et al. "Thymidylate synthase mRNA levels are increased in liver metastases of colorectal cancer patients resistant to fluoropyrimidine-based chemotherapy" BMC Cancer 4:11 (2004)	
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Examiner Signature		Date Considered		
*EXAMINER: Initi	al if reference considered, whether or not citation is in conformance with MDED 600. Dra	w line through citation if not in	conformance and not considered	

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process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including pathering, preparing, and submitting the completed application from to the USPFO. Time will vary depending unon the individual case. Any comments on the rint or if in every respirate this form and/or suggestions for reducing this surview, should be sent to the Chief Information Officer, U.S. Patient and Trademark Office, P.O. Box 1450, Alexandria, VA 2313-1450, DNOT SERD FEES OR COMPLETED FORMS TO THIS ADDRESS. SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients, P.O. Box, Alexandria, VA 2313-1450, DNOTESS SERD TO: Commissioner for Patients,

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	NON PATENT LITERATURE DOCUMENTS						
Examin er Initials*	Cite No.1						
	D41	LOOK et al. "Increased thymidine kinase and thymidylate synthase activities in human epithelial ovarian carcinoma" Anticancer Res. 17:2353-2356 (1997)					
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*EXAMMER: Initial inferience considered, whether or not classion is in conformance with MFEP 600. Draw line through classion in in originate considered, include copy of this form with ensor communication to applicate. I Applicant's superior classion design on the conformance and not considered at www.uspin.gov or MFEP 801.04. Set his Chief to USEPT Patent Documents at www.uspin.gov or MFEP 801.04. Set his Chief to USEPT Patent Document, by the hor deliver code (WFEP 50 sets) and sets and sets

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		NON PATENT LITERATURE DOCUMENTS	
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S. Aller Salaman and a statement country	D56	WOLFE et al. "Antibody-directed enzyme prodrug therapy with the T268G mutant of human carboxypeptidase A1: in vitro and in vivo studies with prodrugs of methotrexate and the thymidylate synthase" Bioconjugate Chemistry 10(1):38-48 (1999)	

Examiner Signature	Date Considered	

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